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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Curtiss III et al.	Group No.:	1645
Serial No.:	09/686,499	Atty. Docket No.:	5316-1192
Filed:	October 11, 2000		
For:	Functional Balanced-Lethal Host-Vector Systems	Examiners:	Khatol S. Shahnan Shah

Declaration of Daniel A. Portnoy Pursuant to 37 C.F.R. §1.132

I, Daniel A. Portnoy, declare and state as follows:

1. All of the statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true.

2. I am the first named inventor of U.S. Patent No. 6,004,815, referred to as 'Portnoy et al.' in the Office Action of 4/22/2004 in the above identified Patent Application.

3. I have reviewed the above identified patent application, and the Office Action of 4/22/2004, and in particular the Patent Office's assertions that

"DAP is required for viability of the microorganism. Therefore Portnoy et al. teach an essential gene that encodes a function that is required for viability. In regard to the recombinant complementing gene on an extra chromosomal vector the applicant attention is directed to Table 2. The plasmid pDP3615 carrying strain MC4100 (DE3) an RNA polymerase essential gene. Portnoy also recite in column 3, lines 51-55 'In particular, the polynucleotide may encode a transcription factor, whereby expression of the transcription factor in the target cell provides activation or de-activation of targeted gene expression in the target cell. Thus Portnoy reference teaches each element of the claimed invention."

4. It is my opinion that the above assertions are not consistent with what a skilled bacteriologist would understand the teachings of the '815 patent to be.

5. Specifically, contrary to the Office's assertion above, none of the plasmids in Table 2 or anywhere else in the specification of the '815 patent comprise a "complementing gene...wherein said complementing gene...is a functional replacement for said essential gene." That phrase describes a gene that encodes a function that is required for cell viability, where that function is the same as that encoded by a native chromosomal gene that has been rendered non-functional. Thus, the complementing gene encodes the same function as the native chromosomal gene that has been rendered non-functional. None of the plasmids described in the '815 patent comprise such a gene.

6. I understand that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. §1001) and may jeopardize the validity of the application or any patent issuing thereon.



Daniel A. Portnoy, Ph.D.

September 20, 2004

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